IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/FENFLURAMINE/ DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO: SHEILA BROWN, ET AL. V. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION No. 99-20593

CLASS COUNSEL'S MEMORANDUM OF LAW IN RESPONSE TO MOTION OF KATHRYN CHAMBERLAIN AND LEO MANNING FOR INCLUSION IN CATEGORY ONE OF THE SEVENTH AMENDMENT TO THE NATIONWIDE CLASS ACTION SETTLEMENT AGREEMENT

I. STATEMENT OF FACTS

Kathryn Chamberlain (DDR # 8262017) and Leo Manning (DDR # 8262069) seek inclusion in Category One of the Seventh Amendment to the Nationwide Class Action Settlement Agreement. Eligibility for inclusion in Category One is governed by § III.A.1. of the Seventh Amendment, which in pertinent part, provides:

> 1. "Category One" consists of all Diet Drug Recipients (or their Representative Claimants) who:
>
> a. Have signed a Pink form, a Blue form, and/or Part I of a Green Form, and submitted it to the Trust on or before May 3, 2003, and/or on whose behalf a Green Form Part II was substantially completed as further described in Section III.A.1.b(2), signed and submitted by an Attesting Physician to the Trust on or before May 3, 2003; and
>
> b. (i) **In the case of any Class Members who have exercised an Initial, Intermediate, or Back-End Opt-Out right under the Settlement Agreement, have submitted a Green Form to the Trust before May 6, 2004**, and (ii) in the case of any other Class Member, have submitted a Green Form to the Trust, or pursuant to

Section XIV.C.4, submits a Green Form to the Trust before the end of the Seventh Amendment Opt-Out/Objection Period:

(1) In which Part I was signed by the Class Member and in which Part II was signed by an Attesting Physician; and

(2) **In which the unaudited answers provided by the Attesting Physician in Part II of the Green Form contain sufficient information on medical conditions to support a claim for Matrix Compensation Benefits on Matrix Level I and/or Matrix Level II of the Settlement Agreement**...; and (emphasis added)

* * * * * * * *

For those Class Members who had exercised an opt-out these Sub-Sections of the Seventh Amendment provide that in order for them to be eligible to be a member of Category One of the Seventh Amendment, they needed to have submitted, *inter alia,* a Green Form **by May 6, 2004 in which Part II attests to the Class Member having medical conditions that support a Matrix Level I and/or II Claim**.

Neither of the moving Class Members had on file with the AHP Settlement Trust by May 6, 2004, a Green Form Part II that met the requirements of Sec. III.A.1.b.(2), above. Though each filed a Green Form in May 2003, the unaudited answers to Part II for each, did NOT contain "sufficient information on medical conditions to support a claim for Matrix Compensation Benefits on Matrix Level I and/or Matrix Level II of the Settlement Agreement."

Part II of the Green Forms that each filed in May 2003 alleged Moderate Mitral Regurgitation, but neither alleged the presence of a complication factor that would have facially qualified either Claim for Matrix Level I and/or II benefits. As for each of the relevant complication factors for a Matrix Level I and/or II Claim based on Moderate Mitral Regurgitation, the answers provided by the attesting doctors to each such question for each claim, was "NO". The provision

of "NO" answers by the attesting doctors resulted in a determination that neither Class Member met the requirements of the Seventh Amendment for their inclusion in Category One.

Part II of the Green Forms that these Class Members submitted in May 2003 were complete, i.e., they were not missing answers to relevant questions. Because they were fully complete, the Trust did not need to issue a deficiency letter advising them that their Claims could not be processed because of an absence of information that was necessary to Claim processing.

For purposes of Category One inclusion, May 6, 2004 is the operative date for assessing the medical information attested to in these Class Members' Green Forms Part II, because each had exercised an intermediate opt-out by May 3, 2003.[1] In moving for inclusion in Category One, these Class Members do not dispute that as of May 6, 2004, their Green Forms Part II did not meet the Seventh Amendment requirements for their inclusion in Category One.

On November 23, 2004, the Trust issued Tentative Determinations constituting facial denials of the May 2003 Green Form Claims for both of these Class Members, on the basis that the Green Forms did not facially allege a Matrix Level I and/or II Claim. The Trust was permitted to issue such

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[1]These Class Members also filed Requests for Inclusion in Category One by November 9, 2004, the date which corresponds to the "end of the Seventh Amendment Opt-Out/Objection Period," purportedly in response to their ascertaining that they were not included in the Initial Category One List published in September 2004. But the Requests for Inclusion that they submitted were duplicate copies of the previously filed Green Forms Part II, that were facially deficient. Further, because these Class Members had previously filed intermediate opt-outs, they are bound by the May 6, 2004-deadline that applies to Class Members who had exercised an intermediate opt-out. Thus, these Class Members could not make a Request for Inclusion under Sec. XIV.C.4 of the Seventh Amendment because of the limitation imposed by Sec. III.A.1.b(i). Class Counsel previously discussed the May 6, 2004-limitation for inclusion in Category One for Class Members who had filed an intermediate opt-out. *See* Class Counsel's Memorandum of Law in Response to Certain Claimants Represented by Baron & Budd's Amended Memorandum in Support of Inclusion in Category One of the Seventh Amendment to the Nationwide Class Action Settlement Agreement (filed February 16, 2006, *Brown* docket at Document No. 2484)(hereinafter referred to as "Class Counsel's Baron & Budd Response").

facial denials without first submitting the Claims to audit pursuant to Pretrial Orders 2662 and 2807, because the answers provided by the attesting doctors in each did not facially demonstrate that either Claim met the medical condition requirements of the Settlement Agreement for a Matrix Level I and/or II Claim.

Both Class Members contested the Tentative Determinations/facial denials by the Trust by submitting "corrected" Green Forms Part II wherein the previously provided "NO" answer to question F.5 relating to whether either suffered from an enlarged left atrium, was now answered as "Yes." The Trust denied the contests and issued Final Determination letters denying the Matrix Claims. These "corrected" Green Forms Part II were based on the same echocardiograms on which the original Green Forms Part II were based and attested to by the same physicians who completed the original Green Forms Part II. The "corrected" Green Forms Part II were not accompanied by an affidavit of the attesting doctors explaining the "error," though Baron & Budd explains in the their cover letter to the Trust accompanying the filings that the underlying echocardiogram written reports for each of these two Class Members reported on the presence of an enlarged left atrium, and therefore the "NO" answers to question F.5 was inadvertent.[2]

In seeking inclusion in Category One, these Class Members argue that the original Green Forms were incorrectly completed by their attesting doctors, who intended to answer the question relating to whether the Class Member suffered from an increased left atrium as "Yes," but inadvertently answered such question as "No." They state that had the Trust denied the original Green Forms at an earlier date, for example shortly after the filings in May 2003, they would have

[2]A copy of the written echocardiogram report for each claim showing the presence of an enlarged left atrium had been provided to the Trust.

had an opportunity to have filed different or corrected Green Forms prior to the May 6, 2004 date that limits their eligibility for inclusion in Category One.

They also argue that the Trust did not meet the obligations imposed upon it by the terms of the Settlement Agreement to timely notify them that their claims were facially deficient and to notify them that their claims were missing information necessary to support a Claim for Benefits. Finally, they argue that the "corrected " Green Forms filed on December 7, 2004 and December 22, 2004 as their contests to the Tentative Determination Denials, should be accepted and relate back to the dates of their filing of their original Green Forms around May 2003, so as to be deemed filed prior to the May 6, 2004 deadline imposed by Sec. III.A.1.b(i) of the Seventh Amendment.

To the extent the arguments made by these Class Members seek to invoke the principle of excusable neglect, Class Counsel will rely on the previously filed memoranda of law addressing that issue in the context of requests for inclusion in Category One.[3]

To the extent that these Class Members argue that the Trust failed to properly process their claims by not "second guessing" the answers provided by attesting physicians and by failing to abide by processing deadlines imposed by the Settlement Agreement, Class Counsel respond as follows.

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[3] These Class Members are represented by the law firm of Baron & Budd, which filed two other motions on behalf of other clients of their firm seeking inclusion in Category One of the Seventh Amendment, to which Class Counsel responded. Class Counsel's memoranda discussed their position regarding the applicability of the principle of excusable neglect to requests for inclusion in Category One of the Seventh Amendment, and accordingly, Class Counsel incorporate those pleadings by reference. *See* Class Counsel's Baron & Budd Response, *(Brown* docket, Document No. 2484, filed February 16, 2006), *supra.* and Class Counsel's Memorandum of Law in Response to Certain Claimants' Motion for Inclusion in Category One of the Seventh amendment to the Nationwide Class Action Settlement Agreement (filed February 16, 2006, *Brown* docket at Document No. 2507).

II. ARGUMENT

A. These Class Members Incorrectly Interpret the Settlement Agreement As Imposing an Obligation on the Trust to Ascertain Whether a Fully Complete Green Form Part II Contains an Erroneous Answer Provided by the Attesting Physician

The moving Class Members wrongly interpret the Settlement Agreement as imposing on the Trust an obligation to perform a lay review of complete Green Forms Part II to determine whether the answers provided by the Attesting Physician are erroneous. No such obligation is imposed on the Trust by the terms of the Settlement Agreement.

They make this argument based on their interpretation of the Settlement Agreement that the obligation off the Trust to issue a deficiency notice to Class Members who submitted an **incomplete** Claim Form, encompasses an obligation to perform a lay review of **complete** Green Forms in an effort to ascertain whether the answers provided by the attesting physician may be erroneous.

Class Counsel agree that the Settlement Agreement imposes on the Trust a processing obligation to determine whether or not a Claim is complete. *See* Settlement Agreement, §VI.C.3.a.

The disconnect in the moving Class Members' argument is their attempt to equate the obligation to ascertain whether a Claim is incomplete as also encompassing an obligation to perform a lay review of complete Claims to ascertain whether the set of complete information provided by an attesting physician is erroneous.

The Settlement Agreement does not impose as a matter of claim processing an obligation on the Trust to "second guess" negative answers provided by the attesting physician to determine whether they are erroneous.[4] Indeed, there are numerous claims that were facially denied by the

[4] The Trust's obligation to audit claims pursuant to Pretrial Orders 2662 and 2807 that contain affirmative attestations that facially support a Matrix Level condition is totally

Trust on the basis that the answers attested to by the attesting physician in the Green Forms Part II did not demonstrate the presence of medical conditions that supported a Matrix Level condition. Many such denials resulted because the Class Member's attesting physician attested to the Class Member suffering from only mild mitral regurgitation, or FDA positive regurgitation without the presence of a complicating factor. To the extent appeals have been taken from such Trust denials, they have been affirmed in arbitration.[5]

The parties to the Settlement Agreement never intended it to be interpreted to impose on the Trust the obligation that these class members claim exists. And, were such an interpretation to be held to be present, it would cause a processing nightmare. In practical terms such an interpretation would then have required the Trust to "second guess" the facial answers provided in every Green Form Part II in order to "create" claims not asserted so that the Claim could be eligible for audit.

Such an interpretation is well beyond the clear intent of the Settlement Agreement and should not be engrafted onto the Agreemenet by bootstrapping off of an entirely different

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distinguishable. Moreover, the only manner in which the Trust could "second guess" a claim that is facially ineligible for Matrix Benefits would have been for it to submit the Claim to audit for a determination by an auditor whether the negative responses should have been in the affirmative. With the history of claims-filing practices here, it is difficult to believe that represented Class Members did not put their "best foot" forward in their Green Form filings, affirmatively alleging each and every condition that they could in support of a Matrix Claim.

[5] *See* Arbitration Decision No. 4 (mild mitral regurgitation denied matrix benefits; Trust determination affirmed); Arbitration Decision No.11 (FDA positive without presence of a qualifying complication factor denied matrix benefits; Trust determination affirmed); Arbitration Decision No. 12 (complication factor without requisite level of regurgitation to support matrix claim denied matrix benefits–later unsworn letter of physician reporting of higher levels of regurgitation and presence of additional complication factors insufficient for matrix benefits; Trust determination affirmed); Arbitration Decision No. 21 (Moderate Mitral Regurgitation without assertion of complication factor denied matrix benefits–presence of FDA positive Mitral regurgitation without complicating factor insufficient; Trust determination affirmed).

responsibility imposed on the Trust to afford Class Members who submitted an **incomplete** Claim notice of a deficiency so that they could supply **missing** information to allow for the further processing of the Claim to a determination.

In sum, the argument that these Class Members make, that their facially complete Green Forms Part II should have been evaluated by the Trust for whether the attesting physician's really meant to provide the "NO" answers given, simply does not make sense.

B. The Processing Deadline Imposed by the Settlement Agreement for Making Determinations of Green Form Claims for Matrix Benefits was Suspended by Pretrial Orders 2663, 2881[6] and 3185

Movants also allege that the Trust failed to timely issue tentative determinations on their Claims for Matrix Benefits. But in making this argument, they fail to recognize that processing deadlines relating to Claims for Matrix Benefits that were imposed by the Settlement Agreement were suspended by a series of Pretrial Orders commencing with PTO 2663 entered well before their Claims were submitted.

On December 3, 2002, the Court entered Pretrial Order No. 2663, which, in pertinent part, suspended the deadlines imposed on the Trust for the processing of Fund A and Fund B claims under § VI.C.3.a.2-4 of the Settlement Agreement, except for the requirement to provide a Class Member with the unique identifying number assigned to the claim within 30 days of the receipt of a Claim.

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[6]In addition, Pretrial Order 2983 established a briefing schedule related to the Trust's Motion for approval of its Operations Plan. The Plan proposed that the Trust would, *inter alia,* prioritize its processing of Green Forms submitted, implement a Claims Integrity Program and attempt to audit each month minimum volumes of facially eligible and completed Green Form claims for Matrix Benefits. The effect of this pretrial order and the events of that time, was to continue the suspension of the Trust's obligation to process completed Green Form Claims within the deadlines imposed by the Settlement Agreement.

See PTO 2663 at ¶ 1(a). The effect of that suspension was to relieve the Trust from determining whether a Claim was complete within 30 days of its receipt.

However, ¶ 2 of PTO 2663 did not relieve the obligation of the Trust to make tentative determinations of claims that the Trust determined to be complete, within the applicable time periods provided for by the Settlement Agreement.

In essence, what these two paragraphs of PTO 2663 do, is on the one hand, relieve the Trust from making completeness determinations within the time frames dictated by the terms of the Settlement Agreement, but on the other hand, retain the obligation that the Trust make tentative determinations within the time frames dictated by the terms of the Settlement Agreement *once the Trust determines a Claim is in fact complete.*

So, pursuant to these paragraphs of PTO 2663, the Trust was afforded virtually unbounded time to determine whether a matrix claim was in fact complete, but the Trust remained bound by the original deadlines of the Settlement Agreement to issue tentative determinations once the completeness determination was made.

In the context of the instant matter, where the Class Members submitted their Green Forms around May 2003, the Trust was not obligated to make a tentative determination within the deadlines imposed by the Settlement Agreement after the trust's receipt of the Claims, but only within the deadlines imposed by the Settlement Agreement *once* the completeness determination was made.

On June 3, 2003, the Court entered Pretrial Order No. 2881 which extended the suspension of processing deadlines of Pretrial Order No. 2663, subject to the requirement that the Trust "process to determination and/or referral to audit all claims within sixty (60) days of the date that claims are

determined to be complete and timely notify claimants under Sections VI.C.4.e and VI.C.4.f. of the Settlement Agreement." *Id.* at ¶ (2)(c). Pretrial Order No. 2881 once again afforded the Trust virtually unbounded time to determine whether a Matrix Claim was complete, though it also retained the obligation that the Trust render a determination on the Claim after the Trust made its completeness determination.

Then, on December 19, 2003, by Pretrial Order No. 3185, the Court further extended the suspension of processing deadlines until February 29, 2004.[7]

In sum, the Trust was relieved by these pretrial orders from having to issue tentative determinations on Matrix Claims within 30 days of **receipt** of a complete Claim. Instead, the Trust was afforded unbounded time to ascertain whether a Claim was complete, and only after it made that determination, was it required to issue a determination within a defined period of time.[8]

III. CONCLUSION

Class Counsel disagree with the moving Class Members' interpretation of the Settlement Agreement that the Trust was required to "second guess" facially complete Matrix Claims to determine if the answers provided by the attesting physician were the answers intended, and to issue a deficiency notice if the Trust believed there was an error. The Settlement Agreement did no more

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[7]On March 30, 2004 Wyeth filed an emergency motion for a temporary stay of processing all Matrix Claims. Pretrial Order 3413, entered on April 8, 2004 established a briefing schedule related to that motion, and ultimately on May 10, 2004, Pretrial Order 3511 was entered that stayed processing pending negotiations leading to the Seventh Amendment.

[8]Class Counsel does not know when the Trust may have made a completeness determination of these Claims, so as to have triggered running of the time within which to then issue a tentative determination. Certainly, if the Trust had identified these Claims as being "complete" well before May 6, 2004, and then failed to issue a tentative determination within the required time to do so, then these facts could be relevant to the determination of whether these Class Members may be entitled to relief under the excusable neglect principle.

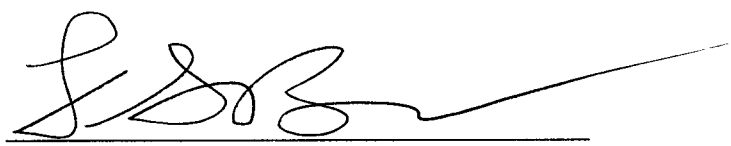
than to require the Trust to review claims for completeness, to process those that were complete, and to issue deficiency notices for those that could not be processed because they were not complete.

In the instance of the two claims at issue here, since each were facially complete when submitted to the Trust, Class Counsel disagree with movants that the Trust was required to issue a deficiency notice because the complete claims did not facially allege a Matrix Claim.

Further, these Class Members were not deprived of the opportunity to review the Green Form claims that they submitted in May 2003 to determine whether they facially alleged a Matrix Level Claim, and upon a determination that there was an error in the Green Forms submitted, to submit a different Green Form by May 6, 2004. These Class Members had a full one year to take that action, regardless of what processing the Trust may have done on their Claims during that time period.

Date: April 24, 2006

Respectfully submitted,



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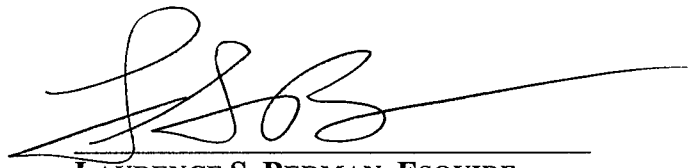
CERTIFICATE OF SERVICE

I, Laurence S. Berman, Esquire, do hereby certify that a true and correct copy of Class Counsel's Memorandum of Law in Response to Motion of Kathryn Chamberlain and Leo Manning for Inclusion in Category One of the Seventh Amendment to the Nationwide Class Action Settlement Agreement has been served on this 24th day of April, 2006 via United States Postal Service, postage pre-paid to the persons on the attached Service List on this date.



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